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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,689	06/20/2006	Kai Schiemann	030863-00011	4470

4372 7590 11/13/2009

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EXAMINER	
DESAI, RITA J	

ART UNIT	PAPER NUMBER
1625	

NOTIFICATION DATE	DELIVERY MODE
11/13/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com
IPMatters@arentfox.com
Patent_Mail@arentfox.com

Office Action Summary	Application No.	Applicant(s)	
	10/583,689	SCHIEMANN ET AL.	
	Examiner	Art Unit	
	Rita J. Desai	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *14-16,18-28 and 35-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,17 and 29-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *10/27* .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

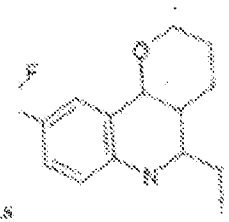
Election/Restrictions

Applicants election of group II of the restriction made by another examiner is noted.

This examiner called Mr. Kamis to further restrict the elected group from the compound, compositions and the methods. He had agreed and elected the compounds. If the compound are found to be allowable the method of treating and a process of making limited to that allowable scope will be rejoined.

For clarification claim 45 should have been included and would now be with the method claims.

IIa Claims 1-13,17, 29-34 drawn to compounds of the formula with the core



and the core is

IIb Claims 14-16 drawn to a process of making the compounds of scope as given in group IIa.

IIc Claims 18 and 19, 35,36 drawn to a mixture of compound along with compound of formula V. A further election of a singe disclosed species is required of IIa and V. This group may be subject to further restriction.

IId Claims 20-25 drawn to a method of treating using the compounds of formula as given in group IIa.

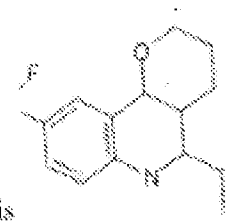
IIe Claims 26-28, 30, 37-38 drawn to a method of treating using the compounds as given in group IIa.

IIf Claims 43 and 44 drawn to a method of treating using compounds of the formula as in group IIa and compounds of formula V. A further election of a singe disclosed species is required of IIa and V. This group may be subject to further restriction.

IIg Claim 45 drawn to a method of in combination with radiation thereapy.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Group IIa is under consideration Claims 1-13,17, 29-34 drawn to compounds of the formula



with the core and the core is .

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13, 17, 29-34 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some compounds of the formula wherein R6 is a phenyl or a thiophene substituted by an alkyl, haogen, acetyl, does not reasonably provide enablement for any aryl or heteroaryl, enabling for compounds of fomula Ia X is O, R2 to be H, R7 to be absent, R1 to be an alkyl and R8 to be H or alkylhydroxy,, R4 and R5 combine to form a six membered ring with an O , does not enable all the confusing substitutents and also the solvates or metabolites. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

1) The breadth of the claims: The instant claims encompass many compounds with a different core and different groups hanging off of it. The core is given by,

And substitutents are

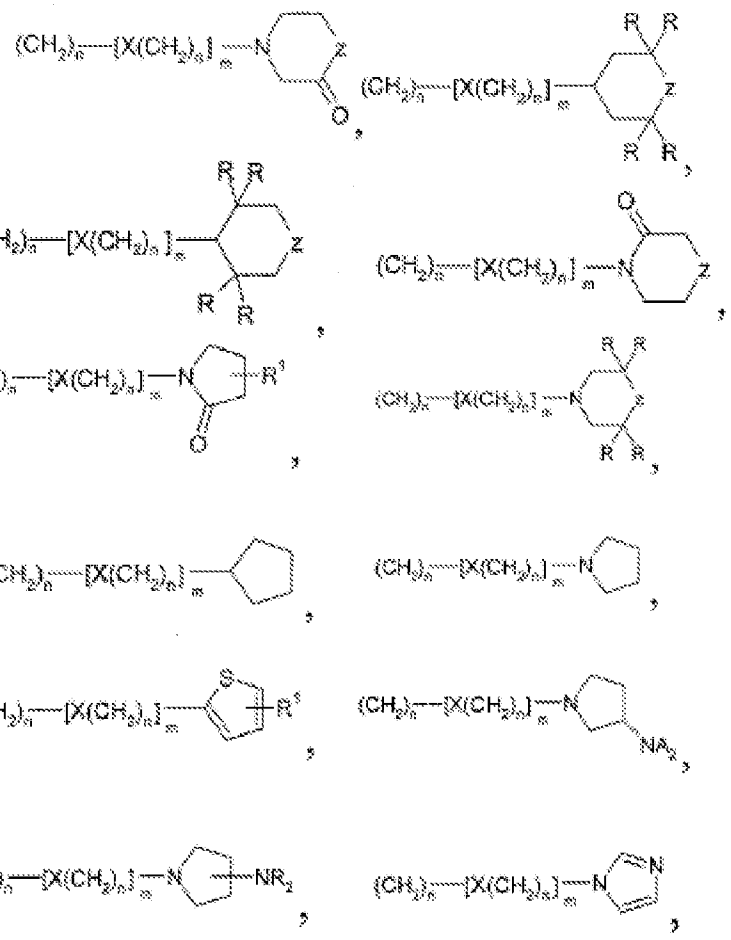
R^1, R^2, R^3, independently of one another, ~~denote~~ are H, R, A, aryl, heteroaryl, Hal, -$(CY_2)_n$-SA, -$(CY_2)_n$-SCF_3, -$(CY_2)_n$-SCN, -$(CY_2)_n$-CF_3, -$(CY_2)_n$-OCF_3, cycloalkyl, -SCH_3, -SCN, -CF_3, -OCF_3, -OA, -$(CY_2)_n$-OH, -$(CY_2)_n$-CO_2R, -$(CY_2)_n$-CN, -$(CY_2)_n$-Hal, -$(CY_2)_n$-NR_2, $(CY_2)_n$-OA, $(CY_2)_n$-OCOA, -SCF_3, $(CY_2)_n$-$CONR_2$, -$(CY_2)_n$-NHCOA, -$(CY_2)_n$-$NHSO_2A$, SF_5, $Si(CH_3)_3$, CO-$(CY_2)_n$-CH_3, -$(CY_2)_n$-N-pyrrolidone, $CH(CH_2)_nNRCOOR$, CHNRCOOR, NCO, $CH(CH_2)_nCOOR$, NCOOR, $CH(CH_2)_nOH$, $N(CH_2)_nOH$, $CHNH_2$, $CH(CH_2)_nNR_2$, $CH(CH_2)_nNR_2$, C(OH)R, CHNCOR, $CH(CH_2)_n$-aryl, $CH(CH_2)_n$-heteroaryl, $CH(CH_2)_nR^1$, $N(CH_2)_nCOOR$, $CH(CH_2)_nX(CH_2)_n$-aryl, $CH(CH_2)_nX(CH_2)_n$-heteroaryl, $N(CH_2)_nCONR_2$, $XCONR(CH_2)_nNR_2$, $N[(CH_2)_nXCOOR]CO(CH_2)_n$-aryl, $N[(CH_2)_nXR]CO(CH_2)_n$-aryl, $N[(CH_2)_nXR]CO(CH_2)_nX$-aryl, $N[(CH_2)_nXR]SO_2(CH_2)_n$-aryl, $N[(CH_2)_nNRCOOR]CO(CH_2)_n$-aryl, $N[(CH_2)_nNR_2]CO(CH_2)_n$-aryl, $N[(CH_2)_nNR_2]CO(CH_2)_nNR$-aryl, $N[(CH_2)_nNR_2]SO_2(CH_2)_n$-aryl, $N[(CH_2)_nXR]CO(CH_2)_n$-heteroaryl, $N[(CH_2)_nXR]CO(CH_2)_nX$-heteroaryl,

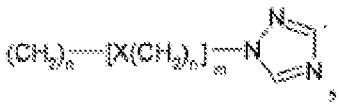
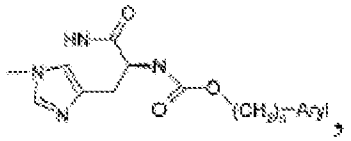
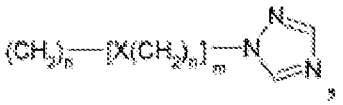
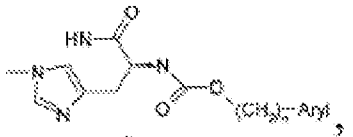
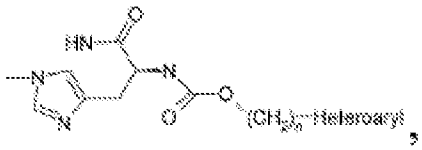
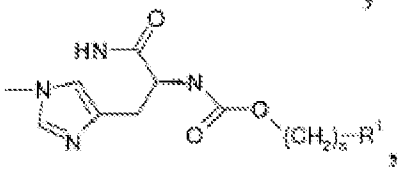
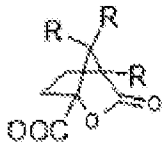
	N[(CH$_2$)$_n$XR]SO$_2$(CH$_2$)$_n$-heteroaryl, N[(CH$_2$)$_n$NRCOOR]CO(CH$_2$)$_n$-heteroaryl, N[(CH$_2$)$_n$NR$_2$]CO(CH$_2$)$_n$-heteroaryl, N[(CH$_2$)$_n$NR$_2$]CO(CH$_2$)$_n$NR-heteroaryl, N[(CH$_2$)$_n$NR$_2$]SO$_2$(CH$_2$)$_n$-heteroaryl, O(CH$_2$)$_n$NR$_2$, X(CH$_2$)$_n$NR$_2$, NCO(CH$_2$)$_n$NR$_2$, or R^1 and R^2 together also are denote -N-C(CF$_3$)=N-, -N-CR=N-, or -N-N=N-,
Y	denotes is H, A, or Hal
A	denotes is alkyl or cycloalkyl, in which one or more H atoms optionally are substituted may be replaced by Hal,
Hal	denotes is F, Cl, Br or I,
R	denotes is H or A, in the case of geminal radicals R together also is –(CH$_2$)$_3$-, -(CH$_2$)$_4$-, –(CH$_2$)$_2$-X-(CH$_2$)$_2$ or –(CH$_2$)$_2$-Z-(CH$_2$)$_n$,
R^4, R^5,	independently of one another, denote are H or an unsubstituted or mono- or poly poly-substituted -OR-, NO$_2$-, Hal-, CF$_3$-, OCF$_3$-, CN-, NR$_2$-, or SR-, aryl-, or heteroaryl-substituted N-pyrrolidone radical, -X-(CH$_2$)$_2$OR, -X-CO(CH$_2$)$_n$CH$_3$, -X-(CH$_2$)$_2$NR$_2$, R^1, S-aryl, O-aryl, CH$_2$Si(CH$_3$)$_3$, or together denote are -X(CR$_2$)$_2$-, -X-(CR$_2$)$_3$-, -X-(CHCH$_2$OR)(CH$_2$)$_2$-, -X-(CHCH$_2$NR$_2$)(CH$_2$)$_2$-, -X(CH$_2$)$_2$NR$_2$, -(CR$_2$)$_3$ -, -(CR$_2$)$_4$-, -CR=CR-CR=CR-, -XCHQ(CR$_2$)$_2$-, -XCHQCR$_2$-, R-N-(C=X)-N-R, or -XC[(CH$_2$)nOR]$_2$CH$_2$CH$_2$-,

X ~~denotes~~ is O, S or NR

Q ~~denotes~~ is CH_2Hal, CHO, COR^a, CH_2R^a, CH_2OCOR^a, CH_2NCOR^1, $CH_2N(R^1)_2$, CH_2OR^1, $CH_2OCON(R^1)_2$, CH_2OCOOR^1, $CH_2NHCON(R^1)_2$, or $CH_2NHCOOR^1$,

R^a ~~denotes~~ is



or,

OR, NHR_2, NR_2, $NR(CH_2)_n$-aryl, $NR(CH_2)_nOR$, COOR, N-pyrrolidone ~~radical~~, OCOR, $NR(CH_2)_nNR_2$, $N[(CH_2)_nNR_2]CO(CH_2)_n$-aryl, $N[(CH_2)_nNHCOOR]CO$-aryl, R^1, $N[CH_2(CH_2)_nOR]_2$, $NR(CH_2)_nNCOOR$, $X(CH_2)_nX(CH_2)_nXR$, $NR[CH_2)_nX(CH_2)_nOH$, $NR(CH_2)_nO(CH_2)_nOH$, $(CH_2)_nCOOR$, $O(CO)NR(CH_2)_nOR$, $O(CO)(CH_2)_nNR_2$, $NR(CH_2)_nNR_2$, $N[(CH_2)_nNR_2]CO(CH_2)_n$-aryl, $N[(CH_2)_nXR]CO(CH_2)_n$-aryl, $N[(CH_2)_nXR]CO(CH_2)_n$-heteroaryl, $N[(CH_2)_nNR_2]CO(CH_2)_n$-heteroaryl, $N[(CH_2)_nNR_2]CO(CH_2)_nR^1$, $N(R)(CH_2)_nN(R)COOR$, $XCOO(CH_2)_nNR_2$, OSO_2A, OSO_2CF_3, OSO_2Ar, $OCONR_2$, or $OCH_2(CH_2)_nNR_2$

Z ~~denotes~~ is CH_2, X, $CHCONH_2$, $CH(CH_2)_nNRCOOR$, CHNRCOOR, NCO, $CH(CH_2)_nCOOR$, NCOOR, $CH(CH_2)_nOH$, $N(CH_2)_nOH$, $CHNH_2$, $CH(CH_2)_nNR_2$, $CH(CH_2)_nNR_2$, C(OH)R, CHNCOR, $CH(CH_2)_n$-aryl, $CH(CH_2)_n$-heteroaryl, $CH(CH_2)_nR^1$,

$N(CH_2)_nCOOR$, $CH(CH_2)_nX(CH_2)_n$-aryl, $CH(CH_2)_nX(CH_2)_n$-heteroaryl, $N(CH_2)_nCONR_2$, $XCONR(CH_2)_nNR_2$, $N[(CH_2)_nXCOOR]CO(CH_2)_n$-aryl, $N[(CH_2)_nXR]CO(CH_2)_n$-aryl, $N[(CH_2)_nXR]CO(CH_2)_nX$-aryl, $N[(CH_2)_nXR]SO_2(CH_2)_n$-aryl, $N[(CH_2)_nNRCOOR]CO(CH_2)_n$-aryl, $N[(CH_2)_nNR_2]CO(CH_2)_n$-aryl, $N[(CH_2)_nNR_2]CO(CH_2)_nNR$-aryl, $N[(CH_2)_nNR_2]SO_2(CH_2)_n$-aryl, $N[(CH_2)_nXR]CO(CH_2)_n$-heteroaryl, $N[(CH_2)_nXR]CO(CH_2)_nX$-heteroaryl, $N[(CH_2)_nXR]SO_2(CH_2)_n$-heteroaryl, $N[(CH_2)_nNRCOOR]CO(CH_2)_n$-heteroaryl, $N[(CH_2)_nNR_2]CO(CH_2)_n$-heteroaryl, $N[(CH_2)_nNR_2]CO(CH_2)_nNR$-heteroaryl, $N[(CH_2)_nNR_2]SO_2(CH_2)_n$-heteroaryl, $O(CH_2)_nNR_2$, $X(CH_2)_nNR_2$, or $NCO(CH_2)_nNR_2$,

R^6 ~~denotes~~ is aryl or heteroaryl, each of which is unsubstituted or mono- or polysubstituted by aryl or heteroaryl, each of which is optionally ~~may be~~ substituted by Hal, NO_2, CN, A, OR, OCOR, COR, NR_2, CF_3, OCF_3, $OCH(CF_3)_2$, ~~or by~~ Hal, NO_2, CN, OR, A, $-(CY_2)_n$-OR, -OCOR, $-(CY_2)_n-CO_2R$, $-(CY_2)_n$-CN, -NCOR, -COR or $-(CY_2)_n-NR_2$,

R^7 ~~denotes~~ is (C=O)-R, (C=O)-NR_2, (C=O)-OR, H or A,

m ~~denotes~~ is 0, 1 or 2,

~~and~~

n ~~denotes~~ is 0, 1, 2, 3, 4, 5, 6 or 7,

Ra is part of Q which is a part of R4 and R5

2) The nature of the invention: The invention is a chemical compound used as a pharmaceutical.

3) The state of the prior art: The state of the prior art is that the drugs and the enzymes react in a lock and key mechanism and the structure of the compound has to be specific. Even a difference of a methyl group verses a hydrogen changes the properties altogether. A good

example is a theophylline verses caffeine. They differ by just a methyl group but one of them has a pharmaceutical use as a bronchodilator. There is no absolute predictability and no established correlation between the different substitutions on a core that they would all behave in the exact same way. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

4) The level of one of ordinary skill: The ordinary artisan is highly skilled.

5) The level of predictability in the art:
How to use:- It is noted that the pharmaceutical art is unpredictable , requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F. 2d 833, 166 USPQ 18(CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statue. The level of unpredictability is in the art is very high. The compounds which differ by a methyl group also show different properties, for e.g. theophylline and caffeine. One of them is a bronchodilator and they differ only by a methyl group. See *In re Fisher*, 166 USPQ 18, at 24 (In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.), *Nationwide Chemical Corporation, et al. v. Wright, et al.*, 192 USPQ 95 (one skilled in chemical and biological arts cannot always reasonably predict how different chemical compounds and elements might behave under varying circumstances), *Ex parte Sudilovsky* 21 USPQ2d 1702 (Appellant's invention concerns pharmaceutical activity. Because there is no evidence of record of analogous activity for similar compounds, the art is relatively unpredictable) *In re Wright* 27 USPQ2d 1510 (the physiological activity of RNA viruses was sufficiently unpredictable that success in developing specific avian recombinant virus vaccine was uncertain).

How to make :-

As stated in the preface to a recent treatise:

"Most non-chemists would probably be horrified if they wereto learn how many attempted syntheses fail, and how inefficient research chemists are. The ratio of successful to unsuccessful chemical experiments in a normal research laboratory is far below unity, and synthetic research chemists, in the same way as most scientists, spend most of their time working out what went wrong, and why. Despite the many pitfalls lurking in organic synthesis, most organic chemistry textbooks and research articles do give the impression that organic reactions just proceed

smoothly and that the total synthesis of complex natural products, for instance, is maybe a labor-intensive but otherwise undemanding task. In fact, most syntheses of structurally complex natural products are the result of several years of hard work by a team of chemists, with almost every step requiring careful optimization. The final synthesis usually looks quite different from that originally planned, because of unexpected difficulties encountered in the initially chosen synthetic sequence. Only the seasoned practitioner who has experienced for himself the many failures and frustrations which the development (sometimes even the repetition) of a synthesis usually implies will be able to appraise such work .....Chemists tend not to publish negative results, because these are, as opposed to positive results, never definite (and far too copious) ....." Dorwald F. A.

Side Reactions in Organic Synthesis, 2005, Wiley: VCH, Weinheim pg. IX of Preface.

Thus it is not very easy to synthesis compounds.

6) The amount of direction provided by the inventor: The inventor provides very little direction in the instant specification. There are very few compounds made as given in claim 13. The reduction to practice does not commenseurate to the scope of the claimed compounds.

The availability of the starting material that is needed to prepare the invention as claimed is at issue here.. As per MPEP 2164.01 (b):
A key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to make the invention are available. In the biotechnical area, this is often true when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening. The Court in In re Ghiron, 442 F.2d 985, 991,169 USPQ 723, 727 (CCPA 1971), made clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. In re Howarth, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981).

There are no starting material provided with respect to all the substitutents .

Regarding solvates:- The claims are drawn to solvates, yet the numerous examples presented all failed to produce a solvate. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 "The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist." The same circumstance appears to be true here. There is no evidence that solvates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that solvates can be made, or limit the claims accordingly.

The claims also recite metabolites. This would be any compound that it would dissociate into so it is not clear what the scope of these metabolites is.

7) The existence of working examples: The instant specification does not have working examples commensurate to the claimed invention.

8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: In view of all the above factors, guidance and state of the art , it would require an undue amount of experimentation to make the invention of the claims with various substituents .

Taking the above eight factors into consideration, it is not seen where the instant specification enables the ordinary artisan to make and/or use the instantly claimed invention.

Genetech Inc Vs Nova Nordisk 42 USPQ 2d 1001.

"A patent is not a hunting license. It is not a reward for search but compensation for its successful conclusion and patent protection is granted in return for an enabling disclosure of an invention , not for vague intimations of general ideas that may or may not be workable."

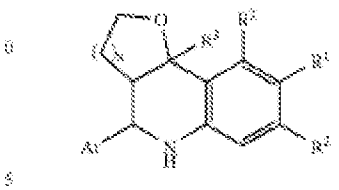
MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was flied, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to practice Applicants' invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

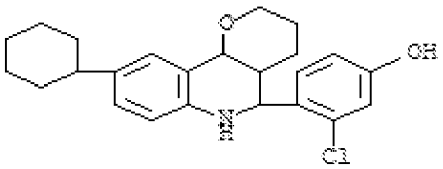
Claims 1-13, 17, 29-34 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9408051 english equivalent US 6001579.



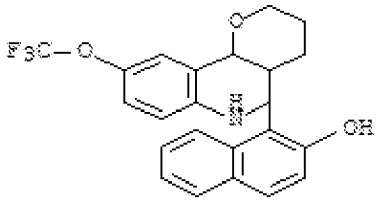
wherein:

See eg 7 column 60 of the US patent. .

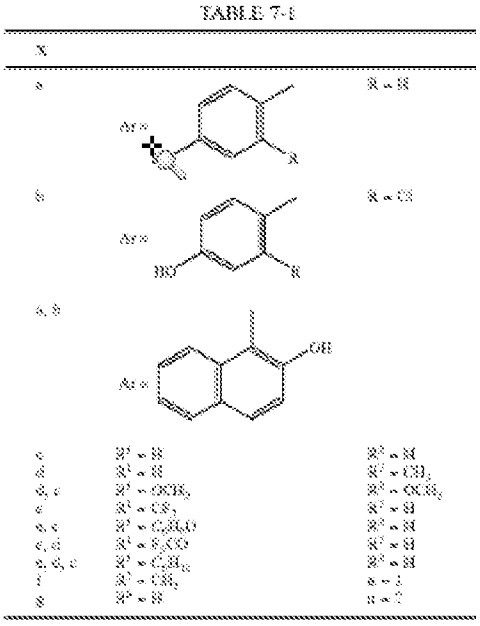
RN 156459-69-7 CAPLUS
CN Phenol, 3-chloro-4-(9-cyclohexyl-3,4,4a,5,6,10b-hexahydro-2H-pyrano[3,2-c]quinolin-5-yl)- (CA INDEX NAME)



RN 156459-70-0 CAPLUS
CN 2-Naphthalenol, 1-[3,4,4a,5,6,10b-hexahydro-9-(trifluoromethoxy)-2H-pyrano[3,2-c]quinolin-5-yl]- (CA INDEX NAME)



These compounds read on the applicants compounds when R6 is an aryl and R2 is a cycloalyl or an –O-CF3



R1 in the prior art can also be various other groups, which are encompassed by applicants R1.

R^1, R^2, R^3, independently of one another, denote H, R, A, aryl, heteroaryl, Hal, -$(CY_2)_n$-SA, -$(CY_2)_n$-SCF_3, -$(CY_2)_n$-SCN, -$(CY_2)_n$-CF_3, -$(CY_2)_n$-OCF_3, cycloalkyl, -SCH_3, -SCN, -CF_3, -OCF_3, -OA, -$(CY_2)_n$-OH, -$(CY_2)_n$-CO_2R, -$(CY_2)_n$-CN, -$(CY_2)_n$-Hal, -$(CY_2)_n$-NR_2, $(CY_2)_n$-OA, $(CY_2)_n$-OCOA,

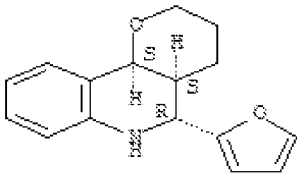
OCF3 , cycloalkyl, CF3, H are all included.

Claims 1-13, 17, 29-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Romauld Baudella et al 1998.

The reference teaches several compounds wherein R6 is a aryl or an hetero aryl. See examples 10-12 on page 4120.

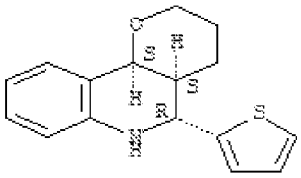
N 206446-84-6 CAPLUS
N 2H-Pyrano[3,2-c]quinoline, 5-(2-furanyl)-3,4,4a,5,6,10b-hexahydro-, (4aR,5S,10bR)-rel- (CA INDEX NAME)

elative stereochemistry.



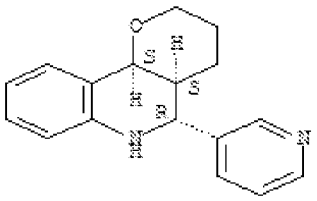
N 206446-85-7 CAPLUS
N 2H-Pyrano[3,2-c]quinoline, 3,4,4a,5,6,10b-hexahydro-5-(2-thienyl)-, (4aR,5S,10bR)-rel- (CA INDEX NAME)

elative stereochemistry.



N 206446-86-8 CAPLUS
N 2H-Pyrano[3,2-c]quinoline, 3,4,4a,5,6,10b-hexahydro-5-(3-pyridinyl)-, (4aR,5S,10bR)-rel- (CA INDEX NAME)

elative stereochemistry.



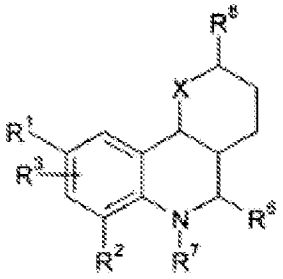
.*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

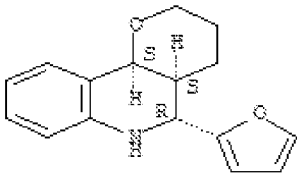
Claims 1-13, 17, 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over R. Baudella et al. 1998.

Applicants claims are drawn to the formula  IA, wherein X is an O, and R6 is an aryl or heteroaryl.

Scope and Content of the Prior art.

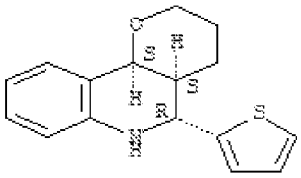
N 206446-84-6 CAPLUS
N 2H-Pyrano[3,2-c]quinoline, 5-(2-furanyl)-3,4,4a,5,6,10b-hexahydro-,
(4aR,5S,10bR)-rel- (CA INDEX NAME)

elative stereochemistry.



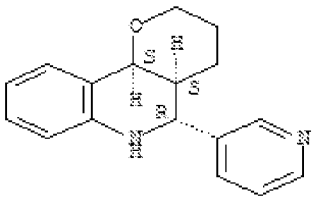
N 206446-85-7 CAPLUS
N 2H-Pyrano[3,2-c]quinoline, 3,4,4a,5,6,10b-hexahydro-5-(2-thienyl)-,
(4aR,5S,10bR)-rel- (CA INDEX NAME)

elative stereochemistry.



N 206446-86-8 CAPLUS
N 2H-Pyrano[3,2-c]quinoline, 3,4,4a,5,6,10b-hexahydro-5-(3-pyridinyl)-,
(4aR,5S,10bR)-rel- (CA INDEX NAME)

elative stereochemistry.



Difference Between the Application and the Prior art.

Most of applicants compounds have an alkyl at the R1 position, whereas the prior art compounds have a H.

See compounds 52, 32 which differ only by an alkyl group.

Prima Facie Obviousness , Rational and Motivation MPEP 2142-2413

One of skill in the art would have been motivated to make the alkyl substituted compounds as H v alkyl is an obvious variant. In re Wood..

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 12/532002

Claims 1-11 of copending application 11/916952

Claim 1 of copending application 11/631185

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same tricyclic core with the same substitutents.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rita J. Desai/
Primary Examiner, Art Unit 1625

November 6, 2009.